

Section 222, act Jan. 19, 1929, ch. 82, §2, 45 Stat. 1085, provided for narcotic farms.

Section 222a, act June 23, 1935, ch. 725, §1, 49 Stat. 1840, provided name for narcotic farm at Lexington, Ky.

Section 222b, act Mar. 28, 1938, ch. 55, §1, 52 Stat. 134, provided name for narcotic farm at Fort Worth, Texas.

Section 223, act Jan. 19, 1929, ch. 82, §3, 45 Stat. 1085; 1939 Reorg. Plan No. I, §205(b), eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1425, provided for an annual estimate of expenses of maintenance of narcotic farms.

Section 224, act Jan. 19, 1929, ch. 82, §4, 45 Stat. 1086, provided for construction of buildings for two of the narcotic farms.

Section 225, acts Jan. 19, 1929, ch. 82, §5, 45 Stat. 1086; June 14, 1930, ch. 488, §4(a), 46 Stat. 586; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, provided for control and management of narcotic farms.

Section 226, act Jan. 19, 1929, ch. 82, §6, 45 Stat. 1086; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for care and treatment of addicts.

Section 227, act Jan. 19, 1929, ch. 82, §7, 45 Stat. 1086, provided for transfer to and from farms of addicts who are prisoners.

Section 228, act Jan. 19, 1929, ch. 82, §8, 45 Stat. 1087, provided that it was the duty of prosecuting officers to report convicted persons believed to be addicts.

Section 229, act Jan. 19, 1929, ch. 82, §9, 45 Stat. 1087; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for employment of addicts.

Section 230, act Jan. 19, 1929, ch. 82, §10, 45 Stat. 1087, provided for parole of inmates.

Section 231, act Jan. 19, 1929, ch. 82, §11, 45 Stat. 1087; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for discharge of addicts.

Section 232, act Jan. 19, 1929, ch. 82, §12, 45 Stat. 1088; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for admission of voluntary patients.

Section 233, act Jan. 19, 1929, ch. 82, §13, 45 Stat. 1088; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for furnishing of gratuities and transportation to discharged convicts.

Section 234, act Jan. 19, 1929, ch. 82, §14, 45 Stat. 1089; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided penalties for introduction of narcotic drugs into a narcotic farm.

Section 235, act Jan. 19, 1929, ch. 82, §15, 45 Stat. 1089, provided penalties for escape of inmates.

Section 236, act Jan. 19, 1929, ch. 82, §16, 45 Stat. 1089, provided penalties for procuring of escape by inmates.

Section 237, act Jan. 19, 1929, ch. 82, §17, 45 Stat. 1089, provided for deportation of alien inmates who are entitled to a discharge from narcotic farms.

#### RENUMBERING OF REPEALING ACT

Section 611 of act July 1, 1944, which repealed this section, was renumbered §711 by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049, §713 by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47, §813 by act July 30, 1956, ch. 779, §3(b), 70 Stat. 720, §913 by Pub. L. 88-581, §4(b), Sept. 4, 1964, 78 Stat. 919, §1013 by Pub. L. 89-239, §3(b), Oct. 6, 1965, 79 Stat. 931, §1113 by Pub. L. 91-572, §6(b), Dec. 24, 1970, 84 Stat. 1506, §1213 by Pub. L. 92-294, §3(b), May 16, 1972, 86 Stat. 137, §1313 by Pub. L. 93-154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93-222, §7(b), Dec. 29, 1973, 87 Stat. 936.

## CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT

### SUBCHAPTER I—SHORT TITLE

Sec.  
301. Short title.

### SUBCHAPTER II—DEFINITIONS

321. Definitions; generally.

Sec.  
321a. "Butter" defined.  
321b. "Package" defined.  
321c. Nonfat dry milk; "milk" defined.  
321d. Market names for catfish and ginseng.  
(a) Catfish labeling.  
(b) Ginseng labeling.

### SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

331. Prohibited acts.  
332. Injunction proceedings.  
(a) Jurisdiction of courts.  
(b) Violation of injunction.  
333. Penalties.  
(a) Violation of section 331 of this title; second violation; intent to defraud or mislead.  
(b) Prescription drug marketing violations.  
(c) Exceptions in certain cases of good faith, etc.  
(d) Exceptions involving misbranded food.  
(e) Prohibited distribution of human growth hormone.  
(f) Redesignated (g)  
(g) Violations related to devices.  
333a. Repealed.  
334. Seizure.  
(a) Grounds and jurisdiction.  
(b) Procedure; multiplicity of pending proceedings.  
(c) Availability of samples of seized goods prior to trial.  
(d) Disposition of goods after decree of condemnation; claims for remission or mitigation of forfeitures.  
(e) Costs.  
(f) Removal of case for trial.  
(g) Administrative restraint; detention orders.  
(h) Administrative detention of foods.  
335. Hearing before report of criminal violation.  
335a. Debarment, temporary denial of approval, and suspension.  
(a) Mandatory debarment; certain drug applications.  
(b) Permissive debarment; certain drug applications; food imports.  
(c) Debarment period and considerations.  
(d) Termination of debarment.  
(e) Publication and list of debarred persons.  
(f) Temporary denial of approval.  
(g) Suspension authority.  
(h) Termination of suspension.  
(i) Procedure.  
(j) Judicial review.  
(k) Certification.  
(l) Applicability.  
(m) Devices; mandatory debarment regarding third-party inspections and reviews.  
335b. Civil penalties.  
(a) In general.  
(b) Procedure.  
(c) Judicial review.  
(d) Recovery of penalties.  
(e) Informants.  
335c. Authority to withdraw approval of abbreviated drug applications.  
(a) In general.  
(b) Procedure.  
(c) Applicability.  
(d) Judicial review.  
336. Report of minor violations.  
337. Proceedings in name of United States; provision as to subpoenas.

### SUBCHAPTER IV—FOOD

341. Definitions and standards for food.

Sec.		Sec.	
342.	Adulterated food. (a) Poisonous, insanitary, etc., ingredients. (b) Absence, substitution, or addition of constituents. (c) Color additives. (d) Confectionery containing alcohol or nonnutritive substance. (e) Oleomargarine containing filthy, putrid, etc., matter. (f) Dietary supplement or ingredient: safety. (g) Dietary supplement: manufacturing practices. (h) Reoffer of food previously denied admission.		(g) Effective date, objections, hearings, and administrative review. (h) Judicial review. (i) Confidentiality and use of data. (j) Status of previously issued regulations. (k) Transitional provision. (l) Harmonization with action under other laws. (m) Fees. (n) National uniformity of tolerances. (o) Consumer right to know. (p) Estrogenic substances screening program. (q) Schedule for review. (r) Temporary tolerance or exemption. (s) Savings clause.
343.	Misbranded food. (a) False or misleading label. (b) Offer for sale under another name. (c) Imitation of another food. (d) Misleading container. (e) Package form. (f) Prominence of information on label. (g) Representation as to definition and standard of identity. (h) Representation as to standards of quality and fill of container. (i) Label where no representation as to definition and standard of identity. (j) Representation for special dietary use. (k) Artificial flavoring, artificial coloring, or chemical preservatives. (l) Pesticide chemicals on raw agricultural commodities. (m) Color additives. (n) Packaging or labeling of drugs in violation of regulations. (o). (p) Repealed. (q) Nutrition information. (r) Nutrition levels and health-related claims. (s) Dietary supplements. (t) Catfish. (u) Ginseng. (v) Failure to label; health threat. (w) Major food allergen labeling requirements. (x) Nonmajor food allergen labeling requirements.	346b. Authorization of appropriations. 347. Intrastate sales of colored oleomargarine. (a) Law governing. (b) Labeling and packaging requirements. (c) Sales in public eating places. (d) Exemption from labeling requirements. (e) Color content of oleomargarine. 347a. Congressional declaration of policy regarding oleomargarine sales. 347b. Contravention of State laws. 348. Food additives. (a) Unsafe food additives; exception for conformity with exemption or regulation. (b) Petition for regulation prescribing conditions of safe use; contents; description of production methods and controls; samples; notice of regulation. (c) Approval or denial of petition; time for issuance of order; evaluation of data; factors. (d) Regulation issued on Secretary's initiative. (e) Publication and effective date of orders. (f) Objections and public hearing; basis and contents of order; statement. (g) Judicial review. (h) Notification relating to food contact substance. (i) Amendment or repeal of regulations. (j) Exemptions for investigational use.	
343-1.	National uniform nutrition labeling.	349.	Bottled drinking water standards; publication in Federal Register.
343-2.	Dietary supplement labeling exemptions. (a) In general. (b) Application. (c) Burden of proof.	350.	Vitamins and minerals. (a) Authority and limitations of Secretary; applicability. (b) Labeling and advertising requirements for foods. (c) Definitions.
343-3.	Disclosure.	350a.	Infant formulas. (a) Adulteration. (b) Requirements for quality factors, good manufacturing practices, and retention of records. (c) Registration of persons distributing new infant formula. (d) Submission of information about new infant formula required. (e) Additional notice requirements for manufacturer. (f) Procedures applicable to recalls by manufacturer; regulatory oversight. (g) Recordkeeping requirements for manufacturer; regulatory oversight and enforcement. (h) Exemptions; regulatory oversight. (i) Nutrient requirements.
343a.	Repealed.		
344.	Emergency permit control. (a) Conditions on manufacturing, processing, etc., as health measure. (b) Violation of permit; suspension and reinstatement. (c) Inspection of permit-holding establishments.		
345.	Regulations making exemptions.		
346.	Tolerances for poisonous or deleterious substances in food; regulations.		
346a.	Tolerances and exemptions for pesticide chemical residues. (a) Requirement for tolerance or exemption. (b) Authority and standard for tolerance. (c) Authority and standard for exemptions. (d) Petition for tolerance or exemption. (e) Action on Administrator's own initiative. (f) Special data requirements.	350b.	New dietary ingredients.

Sec.		Sec.	
	(a) In general.		(s) Devices subject to performance standards not bearing requisite labeling.
	(b) Petition.		(t) Devices for which there has been a failure or refusal to give required notification or to furnish required material or information.
350c.	(c) "New dietary ingredient" defined.		(u) Identification of manufacturer.
	Maintenance and inspection of records.		(v) Reprocessed single-use devices.
	(a) Records inspection.		(w) New animal drugs.
	(b) Regulations concerning record-keeping.	353.	Exemptions and consideration for certain drugs, devices, and biological products.
	(c) Protection of sensitive information.		(a) Regulations for goods to be processed, labeled, or repacked elsewhere.
350d.	(d) Limitations.		(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws.
	Registration of food facilities.		(c) Sales restrictions.
	(a) Registration.		(d) Distribution of drug samples.
	(b) Facility.		(e) Wholesale distributors; guidelines for licensing; definitions.
	(c) Rule of construction.		(f) Veterinary prescription drugs.
SUBCHAPTER V—DRUGS AND DEVICES			(g) Regulation of combination products.
PART A—DRUGS AND DEVICES		353a.	Pharmacy compounding.
351.	Adulterated drugs and devices.		(a) In general.
	(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture.		(b) Compounded drug.
	(b) Strength, quality, or purity differing from official compendium.		(c) Advertising and promotion.
	(c) Misrepresentation of strength, etc., where drug is unrecognized in compendium.		(d) Regulations.
	(d) Mixture with or substitution of another substance.		(e) Application.
	(e) Devices not in conformity with performance standards.		(f) "Compounding" defined.
	(f) Certain class III devices.	354.	Veterinary feed directive drugs.
	(g) Banned devices.		(a) Lawful veterinary feed directive requirement.
	(h) Manufacture, packing, storage, or installation of device not in conformity with applicable requirements or conditions.		(b) Labeling and advertising.
	(i) Failure to comply with requirements under which device was exempted for investigational use.	355.	New drugs.
352.	Misbranded drugs and devices.		(a) Necessity of effective approval of application.
	(a) False or misleading label.		(b) Filing application; contents.
	(b) Package form; contents of label.		(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order.
	(c) Prominence of information on label.		(d) Grounds for refusing application; approval of application; "substantial evidence" defined.
	(d) Repealed.		(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health.
	(e) Designation of drugs or devices by established names.		(f) Revocation of order refusing, withdrawing or suspending approval of application.
	(f) Directions for use and warnings on label.		(g) Service of orders.
	(g) Representations as recognized drug; packing and labeling; inconsistent requirements for designation of drug.		(h) Appeal from order.
	(h) Deteriorative drugs; packing and labeling.		(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary.
	(i) Drug; misleading container; imitation; offer for sale under another name.		(j) Abbreviated new drug applications.
	(j) Health-endangering when used as prescribed.		(k) Records and reports; required information; regulations and orders; access to records.
	(k), (l) Repealed.		(l) Public disclosure of safety and effectiveness data.
	(m) Color additives; packing and labeling.		(m) "Patent" defined.
	(n) Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances.		(n) Scientific advisory panels.
	(o) Drugs or devices from nonregistered establishments.	355a.	Pediatric studies of drugs.
	(p) Packaging or labeling of drugs in violation of regulations.		(a) Definitions.
	(q) Restricted devices using false or misleading advertising or used in violation of regulations.		(b) Market exclusivity for new drugs.
	(r) Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter.		(c) Market exclusivity for already-marketed drugs.
			(d) Conduct of pediatric studies.
			(e) Delay of effective date for certain application.
			(f) Notice of determinations on studies requirement.
			(g) Limitations.
			(h) Relationship to pediatric research requirements.